

Group 8. Forensic Alcohol Analysis

Article 1. General

1215. Authority. These regulations are established pursuant to Sections 100700-100703 of the Health and Safety Code.
- 1215.1 Intent. These regulations are intended to set minimum standards for the practice of forensic alcohol analysis. Agencies engaged in the practice of forensic alcohol analysis may exceed the requirements of these regulations.
- 1215.2 Definitions
- (a) "Alcohol" means the unique chemical compound, ethyl alcohol, with the exception that reference in these regulations to compounds to be avoided as skin antiseptics include the generic class of organic compounds known as alcohols.
 - (b) "Forensic Alcohol Analysis" means the practical application of specialized devices, instruments, and methods by trained personnel to measure the concentration of ethyl alcohol in samples of blood, breath, urine, or tissue of persons involved in traffic accidents or traffic violations.
 - (c) "Breath Alcohol Analysis" means analysis of a sample of a person's expired breath, using a breath testing instrument designed for this purpose, in order to determine the concentration of ethyl alcohol in the person's breath.
 - (d) "Concentration" means the weight amount of alcohol contained in a unit volume of liquid or a unit volume of gas under specified conditions of temperature and pressure; in the case of a solid tissue specimen, "concentration" means the weight amount of alcohol contained in a unit of weight of specimen.
 - (e) "Forensic Alcohol Laboratory" means a place at which specialized apparatus, instruments, and methods are used by trained laboratory personnel to measure the concentration of alcohol in samples of blood, breath, urine, or tissue of persons involved in traffic accidents or in traffic violations; this may be an activity of a laboratory engaged in activities other than Forensic Alcohol Analysis.
 - (f) "Forensic Alcohol Analyst" means a person employed by a forensic alcohol laboratory who performs the technical procedures of forensic alcohol analysis, and meets the qualifications of 1216.2.

- (g) “Method” means the steps used by a trained person to make a measurement of alcohol concentration.
- (h) “Instrument” or “Device” means any item or combination of items of equipment used to make a measurement of alcohol concentration; simple and complex devices are included in this meaning.
- (i) “Sample” or “Specimen” means a representative portion of breath, blood, urine, or tissue or of an artificially constituted material, taken for the purpose of measuring its alcohol concentration.
- (j) “Alveolar” refers to the smallest air sacs in the lungs and to that portion of the expired breath which is in equilibrium with respect to alcohol with the immediately adjacent pulmonary blood.
- (k) “Department” means the California State Department of Health and Human Services and its duly authorized representatives.

Article 2. Qualifications to Perform Forensic Alcohol Analysis

1216. Requirement for qualification to perform Forensic Alcohol Analysis.

- (a) Forensic Alcohol Analysis shall be performed only in laboratories that meet the qualifications set forth in these regulations.
- (b) Forensic Alcohol Analysis shall be performed only by persons who meet the qualifications set forth in these regulations.

1216.1 A laboratory meets the qualifications to perform Forensic Alcohol Analysis by:

- (a) Maintaining a quality control program in forensic alcohol analysis procedures that meets or exceeds the requirements set forth in sections 1218.1 and 1218.2; and,
- (b) Demonstrating satisfactory performance in a proficiency testing program that follows the American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB) proficiency test program guidelines and uses an ASCLD-LAB approved proficiency test provider as specified in the Health and Safety Code Section 100701.
- (c) A laboratory must meet these qualifications at all times that it is engaged in the practice of Forensic Alcohol Analysis.

1216.2 A person meets the qualifications to perform Forensic Alcohol Analysis by:

- (a) Possessing a baccalaureate or higher degree in one of the physical or natural sciences which includes one year (2 semesters or 3 quarters) of general chemistry including lab work.
- (b) Having training and demonstrated competency in performing Forensic Alcohol Analysis. Such training shall include:
 - (1) The methods of alcohol analysis employed in the laboratory;
 - (2) Practical demonstration of the person's ability to perform alcohol analysis;
 - (3) The requirements of these regulations.
- (c) In lieu of (a) and (b) above, a person is qualified to perform Forensic Alcohol Analysis if that person was qualified by the Department of Health Services as a Forensic Alcohol Supervisor or Forensic Alcohol Analyst on or before December 31, 2004.

Article 3. Collection and Handling of Blood, Urine and Tissue Samples

1217. General. Samples taken for forensic alcohol analysis shall be collected and handled in a manner as to ensure that the identity and integrity of the samples are maintained from collection to analysis and reporting.

1217.1 Blood Collection and Retention.

- (a) Blood samples should be collected by venipuncture from living subjects as soon as feasible after an alleged offense and only by persons authorized by Section 23158 of the Vehicle Code.
- (b) Sufficient blood shall be collected to permit duplicate determinations.
- (c) Alcohol or other volatile organic disinfectant shall not be used to clean the skin where a specimen is to be collected. Aqueous benzalkonium chloride (Zephiran) or other suitable aqueous disinfectant shall be used.
- (d) Blood samples shall be collected using sterile, dry hypodermic needles and syringes, or using clean, dry vacuum type containers with sterile needles. Reusable equipment, if used, shall not be cleaned or kept in alcohol or other volatile organic solvent.
- (e) The blood sample shall be deposited into a clean, dry container which is closed with an inert stopper.

- (1) Alcohol or other volatile organic solvent shall not be used to clean the container.
 - (2) The blood shall be mixed with an anticoagulant and a preservative.
- (f) When blood samples for forensic alcohol analysis are collected post-mortem, all practical precautions to insure an uncontaminated sample shall be employed, such as:
- (1) Samples shall be obtained prior to the start of any embalming process.
 - (2) Blood samples shall not be collected from the circulatory system effluent during arterial injection of embalming fluid.
 - (3) The sample should be taken from a major vein or heart. Care should be taken to avoid contamination by alcohol from the gastrointestinal tract directly or by diffusion therefrom.
 - (4) Post-mortem samples shall contain a preservative.
- (g) In order to allow for analysis by the defendant, the remaining portion of the sample shall be retained for one year after the date of collection.
- (1) In post-mortem cases, blood samples shall be retained for at least 1 year after date of collection.
 - (2) Whenever a sample is requested by the defendant for analysis and a sufficient sample remains, the forensic alcohol laboratory or law enforcement agency in possession of the original sample shall continue such possession, but shall provide the defendant with a portion of the remaining sample in accordance with the lab or agency policies and procedures. The samples shall be provided in a clean container together with the identifying information carried on the original sample container to include, at a minimum, the subject's name and a unique numerical identifier.

1217.2 Urine Collection and Retention.

- (a) The only approved urine sample shall be a sample collected no sooner than twenty minutes after first voiding the bladder.

- (b) The specimen shall be deposited in a clean, dry container which also contains a preservative.
- (c) In order to allow for analysis by the defendant, the remaining portion of the sample shall be retained for one year after the date of collection.

(1) Whenever a sample is requested by the defendant for analysis and a sufficient sample remains, the forensic alcohol laboratory or law enforcement agency in possession of the original sample shall continue such possession, but shall provide the defendant with a portion of the remaining sample in accordance with the lab or agency policies and procedures. The samples shall be provided in a clean container together with the identifying information carried on the original sample container to include, at a minimum, the subject's name and a unique numerical identifier.

1217.3 Tissue collection and Retention
(To be determined in committee)

Article 4. Methods of Alcohol Analysis of Blood, Urine, or Tissue

1218. General.

- (a) All laboratory methods used for forensic alcohol analysis of blood, urine, or tissue samples shall be subject to standards set forth in this article.
- (b) Each laboratory shall have detailed, up-to-date, written descriptions of each method it uses for forensic alcohol analysis of blood, urine, or tissue samples.
 - (1) Such descriptions shall be immediately available to the person performing an analysis.
 - (2) Each such description shall include the calibration procedures and the quality control program for the method.

1218.1. Standards of Performance.

- (a) Methods for forensic alcohol analysis of blood, urine, or tissue samples shall meet the following standards of performance:

The method shall be capable of the analysis of a reference sample of known alcohol concentration within accuracy and precision limits of plus or minus 5 percent of the known value of the reference between 0.08% and 0.25% alcohol.

- (1) The method shall be capable of the analysis of ethyl alcohol with a specificity which is adequate and appropriate for traffic law enforcement.
 - (2) The method should be free from interference from anticoagulants and preservatives added to the sample.
 - (3) Blood alcohol results on post-mortem samples shall not be reported unless the oxidizable substance is identified as ethyl alcohol by qualitative test.
 - (4) The method shall give a test result which is always less than 0.010 grams of alcohol per 100 milliliters of blood when living subjects free of alcohol are tested.
- (b) The ability of methods to meet the standards of performance set forth in this article shall be demonstrated by the laboratory quality control program and proficiency testing as required under section 1216.1(a) and 1216.1(b).

1218.2. Standards of Procedure.

- (a) Methods for forensic alcohol analysis shall meet the following standards of procedure.
- (1) The method shall be calibrated with standards, which are water solutions of alcohol.
 - (A) Such alcohol solutions are secondary standards.
 - (B) Each forensic alcohol laboratory shall establish the concentration of each lot of secondary alcohol standards it prepares by an oxidimetric method which employs a primary standard, such as United States National Institute of Standards and Technology (NIST) potassium dichromate; or purchase NIST traceable secondary alcohol standards. Acceptable validation of NIST traceable secondary standards shall include receipt by the laboratory of a certificate of independent analysis verifying the value of the standard, or the laboratory may verify the value by analyzing the new standard concurrently with a previously analyzed standard. Each laboratory's written procedure must specify their quality control protocol for the use of such standards and lots of each standard.
 - (2) The procedure shall include blank and secondary alcohol standard samples at least once each day that samples are subjected to forensic alcohol analysis.

- (A) The blank and secondary alcohol standard samples shall be taken through all steps of the method used for forensic alcohol analysis of samples.
- (3) The procedure shall also include analysis of quality control reference samples as described in Section 1218.3
- (4) The procedure shall include at least duplicate analyses of samples for forensic alcohol analysis.
- (5) A quality control reference sample shall not be taken from the same lot of alcohol solution which is used as a secondary alcohol standard.
- (6) Alcohols or other volatile organic solvents shall not be used to wash or rinse glassware and instruments used for alcohol analysis;
- (7) All instruments used for alcohol analysis shall be in good working order and routinely checked for accuracy and precision.

1218.3. Quality Control Program.

- (a) Methods for forensic alcohol analysis shall be performed in accordance with the following quality control program:
 - (1) For each method of forensic alcohol analysis it performs, each laboratory shall make or acquire a suitable quality control reference material containing alcohol, a sample of which shall be analyzed along with each set of samples; the alcohol concentration in the reference material shall be between 0.080 and 0.200 grams per 100 milliliters of liquid.
 - (2) For each lot of quality control reference material, the laboratory shall determine a mean value of at least 20 replicate analyses, performed over a minimum of 5 separate days, with the method used for analysis of samples for forensic alcohol analysis.
 - (3) Acceptable limits of variation for the method shall be plus or minus 5% of the determined mean.
 - (4) At least one sample of the quality control reference material shall be analyzed with each set of samples analyzed for the purpose of forensic alcohol analysis;
 - (5) Whenever analysis of the quality control reference material is outside the acceptable limits, the analysis shall be regarded to be in error, and the Laboratory will take remedial action to investigate and correct the source of error;

- (6) Until such time as the error has been corrected, as shown by return of the analysis of the quality control reference material to values within the acceptable limits, no samples of blood, urine, or tissue shall be analyzed for the purpose of forensic alcohol analysis.

1218.4. Expression of Analytical Results.

- (a) Analytical results of blood or urine samples shall be expressed as the number of grams of alcohol per 100 milliliters of blood.
 - (1) The symbols, gram(s) %, g%, %, and % (W/V), shall be regarded as acceptable abbreviations of the phrase, grams per 100 milliliters of blood.
- (b) The average of the analytical results shall be reported to the two decimal places, deleting the digit in the third decimal place.
- (c) Blood alcohol concentrations less than 0.01% in living subjects may be reported as negative.
- (d) Blood alcohol concentrations less than 0.02% on post-mortem blood samples may be reported as negative.
- (e) A urine alcohol concentration shall be converted to an equivalent blood alcohol concentration by a calculation based on the relationship: the amount of alcohol in 1.3 milliliters of blood is equivalent to the amount of alcohol in 1 milliliter of urine.
- (f) Analytical results of tissue samples shall be expressed in terms of a weight amount of alcohol in a unit weight of the specimen.

Article 5. Requirements for Breath Alcohol Analysis

1219. General. Evidential breath alcohol analysis shall be performed in accordance with standards set forth in this Article. The Provisions of Articles 3 and 4 do not apply to breath testing.
 - 1219.1. Only such types and models of instruments and related accessories that are approved by U.S. Department of Transportation or are named in the "Conforming Products List" published in the Federal Register by the National Highway Traffic and Safety Administration of the U.S. Department of Transportation shall be used for breath alcohol analysis in this State.

- 1219.2. A breath sample shall be expired breath which is essentially alveolar in composition. The quantity of the breath sample shall be established by direct volumetric measurement.
- 1219.3. Results of breath alcohol analysis shall be expressed as grams of alcohol per 210 liters of breath.
- 1219.4. The breath sample shall be collected only after the subject has been under continuous observation for at least fifteen minutes prior to collection of the breath sample, during which time the subject must not have ingested alcoholic beverages or other substances, regurgitated, vomited, or smoked.
- 1219.5. For each person tested, breath alcohol analysis shall include analysis of 2 separate breath samples which result in determinations of breath alcohol concentrations which do not differ from each other by more than 0.02 grams per 210 liters.
- 1219.6. The accuracy of instruments shall be determined, at a minimum, by periodic analysis of a reference solution or gas sample of known alcohol concentration. For the purposes of such determinations of accuracy, "periodic" means either a period of time not exceeding 10 days or following the testing of every 150 subjects, whichever comes sooner.
- 1219.7. Standards of Performance
- (a) Instruments shall be tested for accuracy by analysis of a reference alcohol/water standard or a dry gas alcohol standard of known concentrations between 0.080 and 0.250 grams/210 liters. The results of such determinations of accuracy shall be within limits of plus or minus 0.010 grams/210 liters of the known value.
 - (b) Each forensic alcohol laboratory shall establish the concentration of each lot of reference standards it prepares by an oxidimetric method which employs a primary standard, such as United States National Institute of Standards and Technology (NIST) potassium dichromate; or purchase NIST traceable reference standards. Acceptable validation of NIST traceable reference standards shall include receipt by the laboratory of a certificate of independent analysis verifying the value of the standard, or the laboratory may verify the value by analyzing the new solution concurrently with a previously analyzed standard. Each laboratory's written procedure must specify their quality control protocol for the use of such standards and lots of each standard.
- 1219.8. Breath results of less than 0.010 grams per 210 liters shall be reported as negative.
- 1219.9. Breath results shall be reported to two decimal places.

1219.10. Breath alcohol analysis shall be performed only with instruments for which the operators have received training and demonstrated competency through written and/or practical examination. Breath alcohol analysis may be performed by operators who do not meet the requirements of a forensic alcohol analyst if they have received training for a specific instrument under a training program supervised by laboratories engaged in the practice of forensic alcohol analysis that is responsible for the maintenance of those instruments. Training may include the use of multimedia presentations, secondary trainers, and/or other methods, as approved by the laboratory. The training of operators shall include at minimum the following subjects:

- (A) Basic theory of operation;
- (B) Detailed procedure of operation;
- (C) Practical experience;
- (D) Written and/or practical examination.

Article 6. Records

1220. General. Forensic alcohol laboratories and law enforcement agencies shall maintain records which clearly represent their activities which are covered by these regulations.

1220.1. Forensic Alcohol Laboratory Records.

- (a) Each laboratory that performs forensic alcohol analysis shall keep the following records for a period of at least five years:
 - (1) An up-to-date record of persons in its employ who are qualified to perform forensic alcohol analysis; the record shall include the qualifications of each such person, including education, experience, training and performance in proficiency and competency tests and examinations;
 - (2) Records of samples analyzed by that laboratory under these regulations, their results and the identity of persons performing the analyses;
 - (3) Records of the quality control program;
 - (4) Records of laboratory performance evaluation in alcohol analysis as shown by results of proficiency tests;
 - (5) Records of such determinations of accuracy of breath testing instruments as a laboratory may perform for law enforcement agencies;

- (6) Records of such training as a laboratory may provide to persons who operate breath testing instruments for law enforcement agencies.

1220.2. Evidential Breath Alcohol Analysis Records.

- (a) Each agency shall keep for a period of at least five years the following records for breath testing instruments which are under its jurisdiction:
 - (1) Records of instrument determinations of accuracy;
 - (2) Records of subject tests performed, results and identities of the persons performing analyses;
 - (3) Records of all maintenance and accuracy tests performed on each instrument;
 - (4) Records of all operators trained by the agency, including the names of instructors and the date of the training.